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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,436	08/21/2003	Martin Gleave	UBC.P-030	9171

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER
1635	
MAIL DATE	DELIVERY MODE
02/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,436	GLEAVE ET AL.	
	Examiner	Art Unit	
	KIMBERLY CHONG	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,10,11,14,20,23,29 and 35-37* is/are pending in the application.

4a) Of the above claim(s) *20,23,29 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,10,11,14,35,36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 10/22/2009 has been considered. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. With entry of the amendment filed on 10/22/2009, claims 1, 4, 10, 11, 14, 20, 23, 29 and 35-37 are pending in the application. Claims 1, 4, 10, 11, 14, 35 and 36 are currently under examination and claims 20, 23, 29 and 37 are withdrawn as being drawn to a non-elected invention

Response to Applicant's Arguments

Claim Rejections - 35 USC § 103

The rejection of claims 1, 4, 10, 11 and 14 under 35 U.S.C. 103(a) as being unpatentable over Miyake et al. (Clinical Cancer Research 2000 cited on Applicant's IDS filed 03/31/2004), Tuschl et al. (US 2004/0259247) and Holen et al. (Nucleic Acid Research 2002).

New claims 35 and 36 would have been rejected in the previous rejection because they recite sequences that were included in the previous rejection. Thus the response to Applicant's arguments is applied to these new claims.

Applicant's arguments filed 10/22/2009 have been fully considered but they are not persuasive. Applicant argues the antisense molecule of Miyake et al. is two bases

shorter than the claimed sequence of SEQ ID No. 10. Applicant further argues that the Examiner has not offered any reason why a skilled artisan would use antisense as a starting point to develop a siRNA inhibitor because the mechanism of each molecule is different. Tuschl et al. according to Applicant do not contain any guidelines on the selection of target sites within a target gene sequence. Applicant argues that the claimed sequence does not meet the requirements of step 7 of the methods of selecting a siRNA as taught by Fosnaugh et al. Applicant argues the reference of Holen et al. teach selection of a siRNA based on ribozyme accessibility and not antisense and that siRNA targeting the translation initiation site was essentially inactive.

In response to Applicant's arguments regarding Miyake et al., Miyake et al. specifically identifies an antisense compound as AS ODN#2 which targets the human TRPM-2 translation initiation site as being capable of reducing TRPM-2 expression which is the target site targeted by the claimed SEQ ID No. 10 sequence. Miyake et al. has identified this target site as accessible to binding by an inhibitory molecule and therefore in designing siRNA to a target gene, one would have used this site and further because antisense and siRNA molecules are designed using different lengths of nucleobases, one would have expected the lengths to be different.

With respect to the argument regarding using antisense as a starting point to develop a siRNA, it has been shown in the prior art that that is an efficient way to develop siRNA. Tuschl et al. teach that it was well recognized in the art that siRNA was a more efficient method of silencing gene expression, requiring concentrations far less than the methods of the prior art, such as antisense compounds. Thus one would

have wanted to substitute siRNA for the antisense molecule in methods of reducing TRPM-2 expression to identify efficient therapeutics in the treatment of cancer. In looking to reduce gene expression of TRPM-2, one of ordinary skill in the art would have wanted use the most efficient method to silencing gene expression and would have looked to the teachings of Tuschl et al. and Holen et al. for generation of siRNAs targeted to of TRPM-2 mRNA. Tuschl et al. and Holen et al. teach that production of siRNAs to any target gene is a matter of routine experimentation and optimization and clearly set forth the guidelines to design such molecules.

Fosnaugh et al. teach general selection guidelines for generating siRNA to a target gene and step 7, as referred to by Applicant (actually 0240), describes further analyzing and ranking siRNA according to whether the molecule has overhang regions. The claimed SEQ ID No. 10 does have overhang regions and therefore in selecting this sequence, one could have clearly analyzed this siRNA based on overhang regions.

With respect to Holen et al., this reference was cited to teach the routine nature of identification of an efficient target site by designing multiple siRNA that overlap in sequence targeted to a known specific target region of a gene wherein the target site has been previously identified as a target region for an inhibitory molecule. While Holen et al. found certain siRNA that were inactive to specific regions of a gene this fact would not teach away from using the information to aid in designing multiple siRNA to a target gene to find the optimal molecule. Given that Miyake et al. has identified a target region, one of ordinary skill in the art would have wanted to design multiple siRNAs to this finite region according to Holen et al. and would have been capable of generating a

siRNA having the claimed sequence.

Thus, the rejection of record is maintained.

Re: Claim Rejections - 35 USC § 103

The rejection of claims 1, 4, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Miyake et al. (Clinical Cancer Research 2000 cited on Applicant's IDS filed 03/31/2004), Tuschl et al. (US 2004/0259247), Fosnaugh et al. (US 2003/0143732) and Hammond et al. (Nature Reviews 2001, Vol. 2; pages 110-119) is maintained for the reasons of record and as explained above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact Tracy Vivlemore at 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635